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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,720	11/25/2003	Antonia C. Kaloidis	820.001USU	5764
7590	06/27/2006		EXAMINER	
Thomas J. Monahan, Esq. Monahan & Costello, LLC 4154 Madison Avenue Trumbull, CT 06611			WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/721,720	KALOIDIS, ANTONIA C.	
	Examiner Deborah K. Ware	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 24 April 2006.
- 2a) This action is FINAL.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 13-24 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 5/24/04.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 1-24 are pending.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on May 24, 2004, was filed and received. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Election/Restrictions***

Applicant's election without traverse of Group I, claims 1-12, in the reply filed on April 24, 2006, is acknowledged.

Claims 13-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 24, 2006.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 is rendered vague and indefinite for failing to recite a clear and distinct Markush Group. It is suggested to include —consisting— after "group": at line 2. Also claim 10 is vague and indefinite for the recitation of "cellulose" at line 3 wherein the term

lacks antecedent basis in the claim. Perhaps Applicants intend –cellulase—because “cellulose” is not an enzyme.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8-9 and 11-12 are rejected under 35 U.S.C. 102(a, e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Li et al (US 6376508), cited on enclosed PTO-892 Form.

Claims are drawn to method for treating spinal muscular atrophy (SMA) comprising administering vitamin C and phenol and optionally a carrier (i.e. water, dispersion).

Li et al teach method for treating spinal muscular atrophy (SMA) comprising administering vitamin C and phenol and optionally a carrier (i.e. water, dispersion). Note the title and column 5, lines 49-50 and 59. Further, note at column 6, wherein orange flavoring is disclosed.

The claims are identical to the cited disclosure and are therefore considered to be anticipated by the teachings of the reference. However, in the alternative that there is some unidentified characteristic of the claimed invention for which to provide for some difference then the difference is considered to be so slight as to render the claimed invention obvious over Li et al. In other words, it would have been obvious to select for these ingredients to treat SMA because the reference discloses their use and the instant claims do not exclude the use of other ingredients which may be disclosed by Li et al. In the alternative and in the absence of persuasive evidence to the contrary the claims are rendered *prima facie*.

***Claim Rejections - 35 USC § 103***

Claims 4-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al in view of Izvekova et al (US 6156320) and Wu (US 5595743), also cited on enclosed PTO-892 Form.

Claims are further drawn to a method of treating SMA comprising administering vitamin C and apple pectin or pomace pectin or citrus pectin or *Lactobacillus acidophilus*, or supplemental enzyme such as amylase.

Li et al is discussed above.

Izvekova et al teach fermented nutraceuticals for treating atrophy comprising administering Lactobacillus acidophilus and apple pectin, vitamin C, etc. Note column 4, lines 44-45, and lines 57, 58 and see the abstract. Also note at column 5, lines 36 and 64-65 that the nutraceuticals are used for treating atrophy, etc.

Wu teaches medicinal treatment that includes supplemental enzyme, such as amylase, note the abstract.

The claims differ from Li et al in that Lactobacillus acidophilus and apple pectin as well as supplemental enzyme such as amylase are not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine with Li et al the Lactobacillus acidophilus and apple pectin of Izvekova et al and supplemental enzymes of Wu in order to provide for effective treatment of SMA. These other ingredients are well recognized in the cited prior art for treating effects of atrophy from diseases such as SMA and would have been expected to provide successful results. One of skill would have been motivated to add these ingredients to increase effective treatment of atrophy resulting from SMA. Clearly one of skill would have desired to improve a treatment protocol by adding well known ingredients in combination to obtain successful results. The claims are *prima facie* obvious.

All claims fail to be patentably distinguishable over the state of the art discussed above and cited on the enclosed PTO-892 and/or PTO-1449. Therefore, the claims are properly rejected.

The remaining references listed on the enclosed PTO-892 and/or PTO-1449 are cited to further show the state of the art.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**DEBORAH K. WARE**  
**PATENT EXAMINER**

Deborah K. Ware  
June 24, 2006